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TEST AND EVALUATION OF AN ALTERNATING CURRENT INTERFACE UNIT (ACIU)

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This report has been reviewed and is approved for publication.

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The ACIU is a portable battery charger/eliminator for Physio-Control's LifePak 10 Portable Cardioscope/Defibrillator, Model -43. It was evaluated for use on board aeromedical evacuation aircraft at the request of the Human Systems Program Office, Aeromedical Systems Division, Brooks AFB TX. Based upon evaluation by Aeromedical Research staff members within the Systems Research Branch, the unit is considered conditionally acceptable for use in the aeromedical evacuation environment.

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TESTING AND EVALUATION OF AN ALTERNATING CURRENT INTERFACE UNIT (ACIU)

BACKGROUND

The Alternating Current Interface Unit (ACIU) is intended to support aeromedical evacuation needs by providing 115 Volt Alternating Current (VAC) / 60 - 400 Hertz (Hz) line power converting it to 12 VDC to run the LifePak 10 Cardiac Monitor/Defibrillator, Model -43. The ACIU is designed to replace the LifePak 10 (-43) dependence on battery power and eliminate the "use only on battery power" restriction placed upon the LifePak 10 (-43). Current method of providing power requires carrying extra batteries and a battery charging system to extend operational capabilities. HSC/YAM requested evaluation of the prototype unit.

DESCRIPTION

The Alternating Current Interface Unit (ACIU) is a portable battery charger/ eliminator for use with the Physio-Control LifePak 10 Portable Cardioscope/ Defibrillator. The ACIU uses worldwide and aircraft alternating current (AC) power sources converting it to direct current (DC) power. The DC power simultaneously operates the LifePak 10 and charges up to three installed LifePak 10 Nickel-Cadmium (ni-cad or NiCd) battery packs. The ACIU is intended for use in all operational and environmental profiles supported by the LifePak 10. The ACIU is rectangular shaped with dimensions of 9.2" L X 7.2" W X 3.5" H. The unit is constructed of lightweight extruded aluminum and weighs 6.8 lbs. The ACIU accepts AC power at 100 to 250 VAC, 50 to 400 Hz.

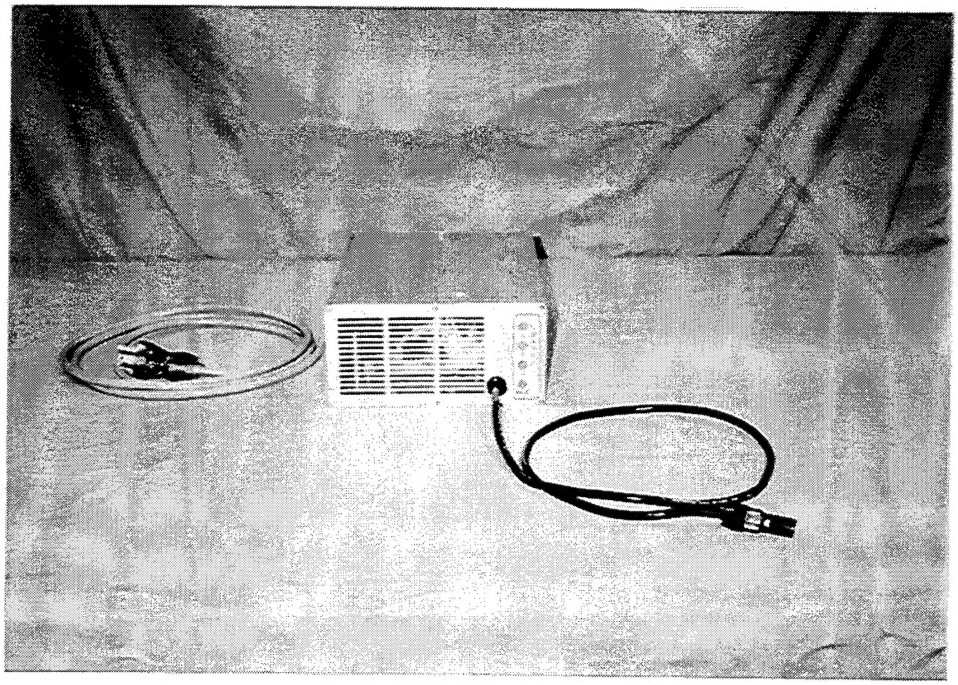

Fig. 1. Alternating Current Interface Unit (ACIU).

METHODS

Test methods and performance criteria were derived from various military standards (Reference List, 1-3, 6-7), nationally recognized performance guidelines (5), ACIU Operational Instructions (8), Emergency Care Research Institute (ECRI) (4), and the Aeromedical Research Procedures Guide (9).

Test Setup

The device operated from two separate input power sources, a 115 VAC / 60 Hz line power, and a 115 VAC / 400 Hz using a variable Behlman ACM Series Oscillator. The ACIU converts the input power from the oscillator into 12V DC power while simultaneously charging the battery circuit and operating the LifePak 10 (-43) Cardiac Monitor/Defibrillator.

Baseline Performance Assessment

The purpose of the Baseline Performance Assessment (BPA) was to quantitatively measure and record the ACIU's performance during standard ambient conditions before adverse environment testing. The BPA was then used as a reference to compare subsequent performance. Initially, it verifie manufacturer specifications and checked for safe operation before testing. Specifically, the BPA included the following:

Initial inspection. The initial inspection checked for quality of workmanship, production techniques, and possible damage incurred during shipment. The unit was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99, Electrical Shock Hazards (AFI 41-203), and Equipment Management in Hospitals (AFI 41-201). Ground resistance and leakage current measurements were made at 60 and 400 Hz. Operation and calibration procedures were verified in accordance with manufacturer's specifications, and the performance check procedures described in the protocol developed by Aeromedical Research staff.

Performance Checks. The following measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. A baseline test consisted of powering the device using 115 VAC / 60 Hz line power and the single phase 400 Hz Behlman ACM Series Oscillator while checking the device against manufacturer's and user-required specifications.

A complete performance test was performed and recorded before, during and after each laboratory test, and parameters were recorded. Values derived from pretest recordings were used as a baseline reference in determining variation in results during each portion of testing. Post-performance check values were used to identify any deviation from the pre-performance check values that might indicate damage to the unit's internal components as a result of testing.

Electrical Safety

Medical Maintenance personnel and Aeromedical Research engineers performed a safety evaluation on all electrical devices to ensure the safety of both the equipment operator and the patient. This assessment involved measuring the equipment's leakage current and ground resistance as well as a general inspection of the device.

Vibration

Vibration tests are designed to determine an item's construction, durability, and performance during worst-case scenario vibrations. The ACIU was subjected to vibration tests in accordance with MIL-STD-810E. Tests consisted of random (11 Hz to 2,000 Hz) and sinusoidal (5 Hz to 500 Hz) curves on X, Y, and Z axes. During sinusoidal tests, the ACIU was operated and vibrated for 5 sweeps of 15 minutes duration (for a total of 75 minutes) on each axis. During random tests, the ACIU was operated and vibrated for 30 minutes on each axis. Before and after each axis, a visual examination of the unit was performed and measurements were recorded.

During vibration testing the ACIU was secured to the vibration table using a NATO Litter simulator equipped with litter equipment brackets and litter straps.

Electromagnetic Interference (EMI)

Electromagnetic Interference (EMI) testing is a primary concern on aircraft and is done IAW MIL-STD 461-D and MIL-STD 462-D. The safety of everyone on board aircraft depends upon control and restriction of excessive EMI emissions from medical devices to aircraft electrical systems. Additionally, the reverse may be true regarding medical devices' susceptibility to aircraft emissions; certain frequencies can cause malfunctions to occur within medical devices. Testing was conducted in the Aeronautical Systems Center's EMI chamber operated by personnel from ASC/ENAI, Wright-Patterson AFB, OH. Tests included the following:

a. Radiated Emissions (RE-102): " Radiated Emissions, Electric Field, 10 kHz to 18 GHz." This test determined the amount of EMI emitted by the equipment during its operation. This test was performed to ensure that the device did not affect other pieces of equipment that may be susceptible to EMI (i.e., aircraft navigation and communication equipment).

b. Conducted Emissions (CE-102): " Conducted Emissions, Power Leads, 10 kHz to 10 MHz." This test measured emissions generated by the components and conducted through the aircraft power lines. This test was performed to ensure that operating the device using line power did not affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103): "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz." This test determined whether or not the Frequency Converter could withstand pre-defined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101): "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz." This test determined whether the components could withstand ripple voltages associated with allowable distortion of power source voltage wave forms.

e. Conducted Susceptibility (CS- 114): "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz." This test was performed to determine whether simulated currents that were developed on platform cabling from electromagnetic fields generated by antenna transmission affected the equipment under test.

f. Conducted Susceptibility (CS-115): "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation." This test was performed to ensure the Frequency Converter would withstand the fast rise and fall time that was present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse.

For all phases of EMI testing and evaluation, the ACIU operated a LifePak 10 Cardiac Monitor/Defibrillator, Model -43. A DynaTech Impulse 4000 Defib/Trans-Q Pacer Analyzer was used to take data from an operating LifePak 10 (-43) to verify the ACIU's ability to supply 12V DC power.

Altitude

The ACIU was tested in the Armstrong Laboratory hypobaric chambers located in Bldg. 160, Brooks AFB TX., to assess the effects of reduced barometric pressure. The testing consisted of operating the ACIU from both 115 VAC / 60 Hz line power, stopping at 2,000 ft intervals up to 10,000 ft to ensure its continued operation and compliance with prescribed operating parameters. The ACIU was given time to stabilize at each altitude after which a complete performance test was accomplished.

Rapid Decompression (RD)

The purpose of this test is to approximate the stress to which medical equipment is exposed during normal, emergency, and accidental decompression. Although, rapid decompressions are uncommon in military transport aircraft, the effect of such an occurrence on a medical item could present a severe safety hazard to the patient, crew, or aircraft operations.

The protocol involved ascending to 8,000 ft at a minimum of 5,000 ft per minute, then decompressing to 40,000 ft in 60 seconds while observing equipment performance. The chamber was returned to ground level and a complete performance test was accomplished. This test was repeated for seven and one second rates of

decompression. The ACIU was placed inside the test chamber. All input and output power cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup were outside the test chamber. Visual observation of the green Light Emitting Diodes (LED's) was done through a window to monitor the unit's function at the time of decompression. The unit was evaluated during and at the end of each RD to see if the device continued to supply power to the LifePak 10 (-43).

Environmental

Environmental test conditions were tailored (based on the aeromedical operational environment) from MIL-STD-810E. These tests measure the system's performance under a range of temperature and humidity conditions encountered during transport. A complete performance test was performed prior to starting and at the end of each test period. The ACIU was placed inside the environmental chamber. At the end of each storage test, the chamber was dehumidified and the temperature adjusted to 20°C (75°F) to return it to existing ambient conditions. The ACIU remained inside the chamber for 30 minutes during this post-test stabilization period, and post-test measurements were taken. For operational testing, the unit was evaluated in the chamber while supplying power to the LifePak 10 (-43) stationed outside of the environmental chamber. Below is a list of the test parameters.

Hot Temperature:	Operation: 49° C ± 2° C (120° F ± 3.6° F) for 2 hours. Storage: 60° C ± 2° C (140° F ± 3.6° F) for 6 hours.
Cold Temperature:	Operation: 0° C ± 4° C (32° F ± 7.2° F) for 2 hours. Storage: -40° C ± 2° C (-40° F ± 3.6° F) for 6 hours.
Humidity:	Operation: 94 ± 4 % relative humidity 29.5° C ± 2° C (85° F ± 3° F) for 4 hours.

Airborne Feasibility

Inflight feasibility tests were conducted to develop and/or verify medical equipment operating procedures and to validate operational performance of the equipment in the actual aeromedical evacuation environment. Inflight testing was conducted on the C-9A and C-141B aircraft.

Setup, securing methods, and integration with aircraft electrical systems were evaluated. The flight crew was encouraged to participate, and their comments are documented and included in the evaluation.

RESULTS

Electrical Safety

The ACIU failed leakage current levels for 115 VAC/400 Hz line power because of excessive leakage current seen during this evaluation. However, the ACIU did perform within the leakage current guidelines on 115 VAC/60 Hz line power. Guidance received from Air Force Medical Logistics Office (AFMLO) requires cardiac monitors/defibrillators using internal or external power supplies to operate **"ONLY"** off 115 VAC/60 Hz power.

Vibration

The 115 VAC / 60-400 Hz power cable became dislodged on three separate occasions during testing, and researchers observed excessive wear to Physio-Control 12V DC power cord following testing. However, the ACIU performed as required and passed vibration evaluation.

Electromagnetic Interference (EMI)

The ACIU passed EMI radiated/conducted emissions and susceptibility limits and was found to be acceptable for use on aeromedical evacuation aircraft.

Altitude

The ACIU supplied line power to the LifePak 10 (-43) without any degradation in LifePak 10 operation. The unit was tested on 115 VAC/60 Hz input power and performed within acceptable limits.

Rapid Decompression (RD)

Under all three test parameters the ACIU maintained line power to the LifePak 10 (-43) with no drop in output power levels. The LifePak 10 was able to deliver 360 joules of energy to the patient simulator.

Environmental

The ACIU operated well during all phases of testing. The unit underwent Hot Storage & Operation and Cold Storage & Operation at a civilian facility under supervision of Aeromedical Research personnel. Humidity testing was accomplished in Bldg. 160, Brooks AFB TX. Performance of the ACIU was within all environmental guidelines.

Airborne Feasibility

The ACIU was powered using the C-9A aircraft's 115 VAC / 60 Hz power supply. On the C-141B the ACIU was powered using a frequency converter, converting 115 VAC / 400 Hz power to 115 VAC / 60 Hz power. This evaluation confirmed that the ACIU will successfully operate the LifePak 10 (-43) model on all aeromedical evacuation aircraft. The unit needs to be protected from weather conditions due to the possibility of water entering through vent holes needed for internal temperature dissipation.

RECOMMENDATIONS

1. Provide **"WARNING"** label instructing user not to use unit on 115 VAC/400 Hz line power because of high leakage current levels seen during this evaluation.
2. Unit requires indoor storage due to vent holes needed to dissipate internal temperature. Allowing exposure to the elements may cause internal damage to the unit and cause an electrical shock hazard.
3. Provide a carrying case to protect the unit during handling.
4. Use a restraining device to keep power cord in place.
5. Move the Physio-Control 12V DC power cord connection on the ACIU up at least 1/4 inch from its present location to prevent excessive wear when using NATO litter equipment brackets.
6. The ACIU is acceptable for use with the Vanner inverter; however, the LifePak 10 (-43) causes a 7-amp power spike when drawing power from the ACIU during the charge phase required for defibrillation. Note, the Vanner inverter can only provide a total of 11 amps output to power medical equipment.

CONCLUSION

Overall, the Alternating Current Interface Unit (ACIU) is considered airworthy on 115 VAC/60 Hz line power. It operates within expected parameters when subjected to environmental extremes and simulated cabin altitudes, and does not produce a hazard to patient or crew during rapid decompression. The ACIU is restricted to use on **115 VAC/60** Hz power **"ONLY"** due to the increased leakage current levels seen during evaluation of 115 VAC/400 Hz power and AFMLO guidance (10) that cardiac monitors/defibrillators can only be used on 115 VAC/60 Hz power.

REFERENCES

1. MIL-STD 461-D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference

2. MIL-STD 462 D, Measurement of EMI Characteristics

3. MIL-STD 810-E, Environmental Test Methods and Engineering Guidelines

4. Emergency Care Research Institute (ECRI), INDEX 1994

5. National Fire Protection Agency, NFPA 99 chapter 7 & 9, Health Care Facilities Code

6. AFI 41-203, Electrical Shock Hazards

7. AFI 41-201, Equipment Management in Hospitals

8. Alternating Current Interface Unit (ACIU) Operating Instructions.

9. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

10. Air Force Medical Logistics Office Letter on The Use of 115 VAC / 400Hz for Cardiac Monitor/Defibrillators dated 21 July 1995.

APPENDIX A

APPENDIX

SPECIFICATIONS AND OPERATING FEATURES OF THE ALTERNATING CURRENT INTERFACE UNIT (ACIU)

Model: Developmental Prototype

Manufacturer: Sunset Resources, Inc.
133. Woodcock Drive Suite 200
San Antonio, Texas 78228

Length: 9.2"

Width: 7.2"

Height: 3.5"

Standard Unit Weight: 6.8 lbs.

Electrical Supply: 100 - 250 VAC/50 - 400 Hz Illumination of 4 green lights lets the user know if the unit is operating and charging the internal batteries of the LifePak 10 (-43)

AC Power Cord: (1) 8' in length

DC Power Cord: (1) 3' in length